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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,633

06/09/2006

Todd Maibach

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

02/14/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/562,633	Applicant(s) MAIBACH, TODD	
	Examiner Lakshmi S. Channavajjala	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-104 is/are pending in the application.
- 4a) Of the above claim(s) 1-16,20-35 and 37-104 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18,19 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of RCE of 1-6-11 is acknowledged.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1-6-11 has been entered.

Claims 1-104 are pending. Claims 18, 19 and 36 have been examined.

Claims 1-17, 20-35 and 37-104 have been withdrawn as being non-elected.

The following rejection replaces the rejection of record:

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 18-19 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6596298 to Leung et al in view of US 5,288,497 to Stanley et al (Stanley) and US 6139847 to Chobanian.

Alternatively,

Claims 18-19 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6596298 to Leung et al in view of US 2007/0184093 to Hang, US 5,288,497 to Stanley et al (Stanley) and US 6139847 to Chobanian.

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Alternatively,

Claims 18-19 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,288,497 to Stanley et al (Stanley) in view of any one of US 6,596,298 to Leung et al in view of US 2007/0184093 to Hang, and further in view of US 6,139,847 to Chobanian.

Leung et al. teach edible films that preferably include pullulan, antimicrobially effective amounts of thymol, methyl salicylate, eucalyptol, menthol; and contain pharmaceutical actives (Abstract, col. 2 summary of the invention). The film more preferably comprises pullulan as a film forming agent in amounts of 45% to 70% (col. 5, L 1-10, col. 11 and examples in col. 17-18) and further Leung suggests incorporating a number of medicaments or pharmacological agents (col. 12). Leung does not teach nitroglycerin and combination of nitroglycerin with other cardiovascular agents.

Hang teaches soluble films comprising a soluble polymer and a strengthening polymer (0017) for delivery of emergency medical care active agents such as nitroglycerin (0019). For the soluble films, Hang preferably teaches pullulan (0030). Hang as well as Leung fails to exemplify a pullulan with nitroglycerin, particularly in the claimed amounts.

Leung or Hang fail to teach an embodiment containing nitroglycerin, in the claimed amounts, and lacks the combination of nitroglycerin with other cardiovascular agents.

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Stanley teaches orally dissolvable medicaments wherein the composition is capable of absorption through the mouth, pharynx and esophagus (abstract), in particular for administering fast acting and potent drugs (col . 5, L 19-25). The medicament of Stanley involves a dissolvable matrix made of carbohydrates, fats or proteins (col. 5, L 43-52). For the active agents, Stanley teaches nitroglycerin in an amount o f 0.4 to 1.0 mg (table 2, l 30-45), which is within the claimed 0.01 mg-100 mg of nitroglycerin. Stanley lacks pullulan film and the combination of cardiovascular agents claimed.

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to incorporate 0.4 to 1.0 mg of nitroglycerin of (Stanley) in the fast dissolving oral film containing pullulan of Leung or Hang because Stanley teaches the above amounts of nitroglycerin as appropriate for incorporating in a medicament matrix that enables fast absorption through mucosal membranes of oral cavity and over come the disadvantages of oral administration by other mechanisms such as frequent swallowing of pills, first pass effect, delay between the administration of tablets etc. Alternatively, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to prepare nitroglycerin dissolvable films with 0.4 to 1.0 mg of nitroglycerin of (Stanley) in the fast dissolving oral film containing pullulan of Leung or Hang because both Leung and Hang teach pullulan films for fast dissolution and for the delivery of oral active agents and Hang particularly teaches the films for nitroglycerin delivery. Further, a skilled artisan would have been able to employ combinations of medicaments for treating cardiovascular conditions with

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nitroglycerin of Stanley in the pullulan films of Hang or Leung, with an expectation to at least achieve an additional protective effect if not a synergistic effect, as suggested by Chobanian et al (abstract, col. 3-4).

Response to Arguments

3. Applicant's arguments filed 1-6-11 have been fully considered but they are not persuasive.

4. Applicants' arguments regarding the teachings of Leung et al, Hang et al and Chobanian have been considered. However, the new rejection now includes the teachings of Stanley et al in addition to the above references. Applicants' argue that in order to solely advance the prosecution, instant claims have been limited to 0.01 mg to 100 mg of nitroglycerin, which is not taught by Leung, hang or Chobanian. However, the argument is not persuasive because the newly added reference suggests the amount of nitroglycerin that should be readily available. Applicants argue that Hang teaches strengthening of water soluble films by making them less soluble that inherently makes them less dissolvable and argues that Hang does not teach rapid dissolving pullulan film. While Hang teaches pullulan as a strengthening polymer and for decreasing the solubility of the first polymer, Hang does not teach preparing insoluble films. Indeed the very invention of Hang is preparing dissolvable films, and the addition of pullulan as a second polymer only gives strength to the 1st polymer, which is otherwise highly soluble. Moreover, Hang also teaches pullulan as a first soluble polymer (0030) and therefore a skilled artisan preparing the films of Hang would only expect soluble and yet

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strong films and not strong and insoluble films. With respect to the argument that Hang teaches away, applicants do not show how the same pullulan (as that of the instant invention) films of Hang teaches a slower solubility than the instant claimed. Further, applicants do not claim any specific solubility in order to distinguish from the solubility of Hang. Applicants argue that Leung and Chobanian fail to remedy the deficiency. However, the evidence that pullulan (of Leung as well as Hang) is soluble comes from the teaching of Leung about the fast dissolving pullulan edible films that are of the same scope as that of the instant and also provide the same transmucosal delivery. However, Chobanian has not been cited for transmucosal delivery and instead cited for the combination of drugs.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
February 13, 2011